

**UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

FEDERAL TRADE COMMISSION;  
STATE OF NEW YORK; STATE OF  
CALIFORNIA; STATE OF ILLINOIS;  
STATE OF NORTH CAROLINA; STATE  
OF OHIO; COMMONWEALTH OF  
PENNSYLVANIA; and  
COMMONWEALTH OF VIRGINIA,

*Plaintiffs,*

v.

VYERA PHARMACEUTICALS, LLC;  
PHOENIXUS AG; MARTIN SHKRELI,  
individually, as an owner and former officer  
of Vyera Pharmaceuticals, LLC and  
Phoenixus AG; and KEVIN MULLEADY,  
individually, as an owner and director of  
Phoenixus AG and a former executive of  
Vyera Pharmaceuticals, LLC,

*Defendants.*

Case No. 1:20-cv-00706-DLC

ECF Case

**DEFENDANT MARTIN SHKRELI'S ANSWER TO PLAINTIFFS' AMENDED  
COMPLAINT FOR INJUNCTIVE AND OTHER EQUITABLE RELIEF**

Defendant Martin Shkreli, by and through his attorneys, submits this Answer to Plaintiffs' Amended Complaint for Injunctive and Other Equitable Relief ("Complaint"). *See* ECF No. 87.

Pursuant to Federal Rule of Civil Procedure 8(b)(3), Mr. Shkreli denies each and every one of the allegations except to the extent those allegations are specifically admitted below. Mr. Shkreli further responds to the allegations in the Complaint as follows:

**I. "Nature of the Case"**<sup>1</sup>

1. Mr. Shkreli admits that Daraprim has been used to treat toxoplasmosis. Mr. Shkreli denies that he is an executive of Phoenixus and/or Vyera (collectively, the "Company"). Mr. Shkreli admits that he is a minority shareholder of Vyera. Mr. Shkreli denies all other allegations in Paragraph 1 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 1 directed toward the Company and/or Kevin Mulleady and on that basis denies them.

2. Mr. Shkreli admits that Daraprim has been sold for more than 60 years and that, in 2015, Vyera acquired the U.S. rights to Daraprim. Mr. Shkreli denies the remaining allegations in Paragraph 2.

3. Mr. Shkreli admits that, as of 2015, Daraprim had no patent protection. Mr. Shkreli denies the remaining allegations in Paragraph 3 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 3 directed toward the Company and Mr. Mulleady on that basis denies them.

4. Insofar as Paragraph 4 alleges that the U.S. Food & Drug Administration ("FDA") requires any generic applicant to conduct bioequivalence testing comparing its product to samples

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<sup>1</sup> The headings in quotation marks are copied from the Complaint for ease of reference. They do not constitute part of Mr. Shkreli's answer. To the extent that responses to the headings are required, Mr. Shkreli denies them.

of the branded drug, that allegation states a legal conclusion to which no response is required. Mr. Shkreli lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 4 concerning generic companies, including whether they could secure enough branded Daraprim for bioequivalence testing and whether any generic company abandoned development plans, and on that basis denies them. Mr. Shkreli denies the remaining allegations in Paragraph 4.

5. Mr. Shkreli admits that, in January 2017, Turing Pharmaceuticals AG (the predecessor to Phoenixus AG) entered into a supply agreement for pyrimethamine with Fukuzyu Pharmaceutical Co, Ltd. (“Fukuzyu”), the terms of which speak for themselves. Plaintiffs refer to an “exclusive supply agreement,” a document in writing, the terms of which speak for themselves, and Plaintiffs’ characterization thereof in Paragraph 5 is therefore denied. Mr. Shkreli denies the remaining allegations in Paragraph 5.

6. Mr. Shkreli admits that the Company executed another exclusive supply agreement with RL Fine Chem Pvt. Ltd. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 6, and on that basis, denies them.

7. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 7, and on that basis, denies them.

8. Mr. Shkreli denies the allegations in Paragraph 8.

## **II. “Jurisdiction and Venue”**

9. Paragraph 9 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 9.

10. Paragraph 10 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 10 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth

of the allegations in Paragraph 10 directed toward the Company or Mr. Mulleady, and therefore, these allegations are denied.

11. Paragraph 11 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 11 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 11 directed toward the Company or Mr. Mulleady, and therefore, these allegations are denied.

12. Paragraph 12 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 12. It is further denied that Mr. Shkreli possesses any “general business practices,” as he has not been employed by the Company in nearly five years.

13. Paragraph 13 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 13.

14. Paragraph 14 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 14 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 14 directed toward Mr. Mulleady, and therefore, these allegations are denied.

### **III. “The Parties”**

#### **A. “Plaintiff Federal Trade Commission”**

15. Paragraph 15 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 15.

16. Paragraph 16 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 16.

**B. “Plaintiff State of New York”**

17. Paragraph 17 states legal conclusions and assertions of intent to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 17.

**C. “Plaintiff State of California”**

18. Paragraph 18 states legal conclusions and assertions of intent to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 18.

**D. “Plaintiff State of Illinois”**

19. Paragraph 19 states legal conclusions and assertions of intent to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 19.

**E. “Plaintiff State of North Carolina”**

20. Paragraph 20 states legal conclusions and assertions of intent to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 20.

**F. “Plaintiff State of Ohio”**

21. Paragraph 21 states legal conclusions and assertions of intent to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 21.

**G. “Plaintiff Commonwealth of Pennsylvania”**

22. To the extent Paragraph 22 states allegations relating to Claim IX(A), that claim has been dismissed by the Court, and thus no response is required. Paragraph 22 contains legal

conclusions and assertions of intent to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 22.

**H. “Plaintiff Commonwealth of Virginia”**

23. Paragraph 23 states legal conclusions and assertions of intent to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 23.

**I. “Corporate Defendants”**

24. Mr. Shkreli admits the allegations in Paragraph 24.

25. Mr. Shkreli admits that Phoenixus AG is engaged in the manufacture and distribution of Daraprim in the United States, that Phoenixus AG sells Daraprim to Vyera Pharmaceuticals, LLC for distribution in the United States, and that Phoenixus AG is involved in the distribution, pricing, and commercial and marketing activities of Daraprim. Mr. Shkreli denies the remaining allegations in Paragraph 25. Mr. Shkreli states that Turing Pharmaceuticals AG (the predecessor to Phoenixus AG) acquired the rights to market and distribute Daraprim in the United States in August 2015, and that Turing Pharmaceuticals AG designated its wholly-owned subsidiary, Turing Pharmaceuticals, LLC (the predecessor to Vyera Pharmaceuticals, LLC), as the exclusive distributor of Daraprim in the United States.

26. Mr. Shkreli admits that Vyera Pharmaceuticals, LLC is a privately-held, for-profit limited liability corporation, is wholly owned by Phoenixus AG, is incorporated in Delaware with its principal place of business located in New York City, transacts business in the Southern District of New York and throughout the United States, and was previously named Turing Pharmaceuticals, LLC.

27. Mr. Shkreli admits that Vyera Pharmaceuticals, LLC is registered with the FDA as the owner of the Daraprim New Drug Application and that Vyera Pharmaceuticals, LLC purchases

Daraprim from Phoenixus AG and then markets and distributes Daraprim throughout the United States.

28. Mr. Shkreli admits that Phoenixus AG has five direct employees, that Averill Powers is the Chief Executive Officer of Phoenixus AG and the Chief Strategy Officer and General Counsel of Vyera Pharmaceuticals, LLC, and that Vyera Pharmaceuticals, LLC has no board of directors. Mr. Shkreli admits that Phoenixus's board of directors controls Vyera, which has no board. Mr. Shkreli denies the remaining allegations in Paragraph 28.

29. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 29, and therefore, these allegations are denied.

30. Paragraph 30 does not contain any allegations of fact to which a response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 30.

**J. "Individual Defendants"**

**1. "Martin Shkreli"**

31. Mr. Shkreli admits that he founded Turing Pharmaceuticals AG (the predecessor to Phoenixus AG) and Turing Pharmaceuticals, LLC (the predecessor to Vyera Pharmaceuticals, LLC), that he is a former chairman of the board of Phoenixus AG, that he is a former CEO of Vyera Pharmaceuticals, LLC, that he is presently reflected as a minority shareholder on the books and records of Phoenixus AG, and that he resided in this District until September 2017. Mr. Shkreli denies the remaining allegations in Paragraph 31. Insofar as Paragraph 31 alleges that Mr. Shkreli is the "largest shareholder" of Phoenixus AG, such allegation states a legal conclusion to which no response is required.

32. Mr. Shkreli admits that he founded hedge funds prior to founding Vyera. Mr. Shkreli denies the remaining allegations in Paragraph 32. Mr. Shkreli further states that Plaintiffs' allegations in Paragraph 32 are immaterial, impertinent and scandalous.

33. Mr. Shkreli admits that he founded Retrophin, Inc. Mr. Shkreli denies the remaining allegations in Paragraph 33. Mr. Shkreli further states that Plaintiffs' allegations in Paragraph 33 are immaterial, impertinent and scandalous.

34. Certain allegations in Paragraph 34 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli denies the remaining allegations in Paragraph 34.

35. Mr. Shkreli admits that he was ousted in 2014 by the board of directors of Retrophin for alleged misconduct, but denies that he committed any such misconduct. Mr. Shkreli subsequently sued the directors for ousting him, and the matter was settled. Mr. Shkreli further states that Plaintiffs' allegations in Paragraph 35 are immaterial, impertinent and scandalous.

36. Mr. Shkreli admits that he founded Vyera after he left Retrophin. Mr. Shkreli denies the remaining allegations in Paragraph 36.

37. Mr. Shkreli denies the allegations in Paragraph 37.

38. Mr. Shkreli admits that he was the CEO of Phoenixus AG and Vyera Pharmaceuticals LLC until his arrest in December 2015, and that he was incarcerated in September 2017. The remaining allegations in Paragraph 38 purport to characterize, summarize, or quote from selected portions of one or more documents relating to court proceedings, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli further states that Plaintiffs' allegations in Paragraph 38 are immaterial, impertinent and scandalous.

39. Mr. Shkreli admits that Ron Tilles served as CEO of Turing Pharmaceuticals AG and Turing Pharmaceuticals, LLC from January 1, 2016 to April 11, 2017 and that Mr. Shkreli is



presently reflected as a minority shareholder on the books and records of Phoenixus AG. Certain allegations in Paragraph 39 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli denies the remaining allegations in Paragraph 39 directed toward Mr. Shkreli. Insofar as Paragraph 39 alleges that Mr. Shkreli is the “largest shareholder” of Phoenixus AG, such allegation states a legal conclusion to which no response is required.

40. Mr. Shkreli admits that Dr. Eliseo Salinas replaced Ron Tilles as interim CEO of Turing Pharmaceuticals, LLC in April 2017. Mr. Shkreli denies the remaining allegations in Paragraph 40 directed toward Mr. Shkreli.

41. Mr. Shkreli admits that Mr. Mulleady and Akeel Mithani joined the board of directors of Phoenixus AG in June 2017 and that Mr. Mulleady formerly served as CEO of Phoenixus AG and Vyera Pharmaceuticals, LLC from January 1, 2018 to February 19, 2019. Certain allegations in Paragraph 41 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli denies the remaining allegations in Paragraph 41 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 41 directed toward the Company or Mr. Mulleady and therefore denies them.

42. Certain allegations in Paragraph 42 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli admits that he suggested to Mr. Mithani that he apply for a job at Vyera. Mr. Shkreli admits that Mr. Mithani

was elected to the board of directors of Phoenixus AG in June 2017. Mr. Shkreli denies the remaining allegations in Paragraph 42 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 42 directed toward the Company and on that basis denies them.

43. Certain allegations in Paragraph 43 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli admits that, in 2017, Phoenixus AG offered to buy back preferred shares from interested investors. Mr. Shkreli denies the remaining allegations in Paragraph 43 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 43 directed toward the Company and therefore denies them.

44. Certain allegations in Paragraph 44 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli admits that since his incarceration, he has communicated with many of his family and friends, including Mr. Mulleady and Mr. Mithani. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegation in Paragraph 44 regarding the number of his emails with Mr. Mulleady and Mr. Mithani between June and December 2019, and therefore denies that allegation. To the extent that the last sentence of paragraph 44, which is ambiguous, alleges that all of Mr. Shkreli's communications with Mr. Mulleady and Mr. Mithani relate to matters of Vyera business strategy, that allegation is specifically denied. Mr. Shkreli denies the remaining allegations in Paragraph 44 directed toward Mr. Shkreli.

45. The allegations in Paragraph 45 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents, and therefore, denies the characterizations alleged in Paragraph 45.

46. Mr. Shkreli admits that he is reflected on the books and records of Phoenixus AG as a minority shareholder, owning approximately [REDACTED] of Phoenixus AG shares and controlling approximately [REDACTED] of shareholder votes.

## **2. “Kevin Mulleady”**

47. Mr. Shkreli admits that Mr. Mulleady is the current chairman of the board of directors of Phoenixus AG and a former CEO of Vyera. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 47 directed toward Mr. Mulleady and therefore denies them.

48. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 48 directed toward Mr. Mulleady and therefore denies them.

49. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 49 directed toward Mr. Mulleady and therefore denies them.

50. Mr. Shkreli admits that Mr. Mulleady took a position finding investors for Mr. Shkreli’s hedge fund, and that Mr. Mulleady helped start Retrophin, Inc., and was an early employee of Turing Pharmaceuticals AG (the predecessor to Phoenixus AG) and Turing Pharmaceuticals, LLC (the predecessor to Vyera Pharmaceuticals, LLC). Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 50 directed toward Mr. Mulleady and therefore denies them.

51. Mr. Shkreli admits that Mr. Mulleady held the position of Managing Director of Turing Pharmaceuticals AG from October 27, 2014 to June 3, 2016. Mr. Shkreli denies the

remaining allegations in Paragraph 51 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 51 directed toward Mr. Mulleady and therefore denies them.

52. Mr. Shkreli admits that Mr. Mulleady joined the board of directors of Phoenixus AG in 2017, that he is currently the Chairman of the board of directors of Phoenixus AG, and that he formerly held the position of CEO of Phoenixus AG and Vyera Pharmaceuticals, LLC. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 52 directed toward Mr. Mulleady and the Company, and therefore denies them.

53. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 52 directed toward Mr. Mulleady and the Company, and therefore denies them.

#### **IV. “Background”**

##### **A. “Federal Law Encourages Generic Competition”**

54. Paragraph 54 purports to summarize various statutes. The text of those statutes speaks for itself. Mr. Shkreli refers to those statutes for a true and complete statement of their meaning.

55. Mr. Shkreli admits that products based on an NDA are generally referred to as “brand-name drugs” or “branded drugs.” The remaining allegations in Paragraph 55 state legal conclusions to which no response is required.

56. Mr. Shkreli admits that a company seeking to market a generic version of a branded drug may file an Abbreviated New Drug Application (“ANDA”) with the FDA referencing the branded drug’s NDA. The remaining allegations in Paragraph 56 state legal conclusions to which no response is required.

57. Paragraph 57 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 57.

58. Paragraph 58 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 58.

59. Paragraph 59 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 59.

60. Mr. Shkreli lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 60 and therefore denies them.

61. Mr. Shkreli lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 61 and therefore denies them.

62. Paragraph 62 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 62. Mr. Shkreli lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 62 and therefore denies them.

63. Mr. Shkreli lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 63 and therefore denies them.

64. Paragraph 64 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 64. Mr. Shkreli lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 64 and therefore denies them.

**B. “Competition from Lower-Priced Generic Drugs Saves American Consumers Billions of Dollars Each Year”**

65. Paragraph 65 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 65. Mr. Shkreli lacks

knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 65 and therefore denies them.

66. Paragraph 66 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 66.

67. Certain allegations in Paragraph 67 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli otherwise lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 67 and therefore denies them.

68. Mr. Shkreli lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 68 and on that basis denies them.

**C. “Daraprim Is the Gold-Standard Treatment for Toxoplasmosis”**

69. Mr. Shkreli admits that toxoplasmosis is a parasitic infection caused by *Toxoplasma gondii* (*T. gondii*), which is typically transmitted through foodborne (eating contaminated meat), animal-to-human (contact with infected cat feces), or mother-to-child (congenital) routes. Mr. Shkreli further admits that, in most infected humans, toxoplasmosis is contained by their immune systems and causes no symptoms. Mr. Shkreli denies as stated the allegation that toxoplasmosis is “common.” Mr. Shkreli states that toxoplasmosis encephalitis, the illness that Daraprim treats, is extremely rare.

70. Mr. Shkreli admits that, in some immunocompromised individuals—such as those with HIV/AIDS, cancer patients, or recipients of organ transplants— an active infection with *T. gondii* may cause severe symptoms, and can in some cases become a potentially fatal organ infection, most commonly in the brain, lungs, or heart. Mr. Shkreli further admits that *T. gondii* can also infect the eyes.

71. Mr. Shkreli admits that if an expectant mother becomes newly infected with *T. gondii* during or just before pregnancy, she can pass the infection to her unborn baby, and such an infection may cause congenital toxoplasmosis, which, if left untreated, may lead to blindness, severe intellectual disabilities, and other neurological problems.

72. Mr. Shkreli lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 72 and therefore denies them.

73. Certain allegations in Paragraph 73 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 73 and therefore denies them.

74. Certain allegations in Paragraph 74 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents.

75. Mr. Shkreli admits that Daraprim is a branded version of pyrimethamine, that Daraprim was first approved by the FDA in 1953, and that Daraprim is no longer subject to patent protection. Mr. Shkreli denies the remaining allegations in Paragraph 75.

76. Mr. Shkreli lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 76 and therefore denies them.

77. Mr. Shkreli lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 77 and therefore denies them.

78. Mr. Shkreli denies the allegations in Paragraph 78.

**D. “Vyera’s Acquisition of Daraprim”**

**1. “Prior ownership of Daraprim”**

79. Mr. Shkreli lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 79 and therefore denies them.

80. Mr. Shkreli lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 80 and therefore denies them.

81. Mr. Shkreli lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 81 and therefore denies them.

82. Mr. Shkreli lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 82 and therefore denies them.

83. Mr. Shkreli lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 83 and therefore denies them.

84. Mr. Shkreli lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 84 and therefore denies them.

85. Mr. Shkreli lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 85 and therefore denies them.

**2. “Vyera’s acquisition of Daraprim”**

86. Certain allegations in Paragraph 86 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those unidentified documents to the extent they exist for a true and complete statement of their contents. Mr. Shkreli denies the remaining allegations in Paragraph 86.

87. Mr. Shkreli admits that, in or around April 2015, Vyera contacted Impax with a bid to acquire the U.S. Daraprim rights for approximately [REDACTED] Mr. Shkreli lacks knowledge



or information sufficient to form a belief about the remaining allegations in Paragraph 87 and therefore denies them.

88. Mr. Shkreli admits that Vyera acquired the U.S. rights to Daraprim in August 2015 for the price of approximately \$55 million. Mr. Shkreli lacks knowledge or information sufficient to form a belief about the remaining allegations in Paragraph 88 and therefore denies them.

89. Mr. Shkreli denies the allegations in Paragraph 89.

90. Certain allegations in Paragraph 90 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli denies the remaining allegations in Paragraph 90 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 90 directed toward the Company and therefore denies them.

91. The allegations in Paragraph 91 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 91 directed toward the Company and therefore denies them.

92. The allegations in Paragraph 92 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 92 directed toward the Company and therefore denies them.

**V. “Defendants’ Anticompetitive Agreements to Maintain Vyera’s Daraprim Monopoly”**

93. Mr. Shkreli denies the allegations in Paragraph 93 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 93 directed toward the Company and Mr. Mulleady and therefore denies them.

**A. “Defendants Implement Agreements Restricting Resale and Limiting Purchases to Block Generic Entry”**

94. Mr. Shkreli lacks knowledge or information sufficient to form a belief about the allegations in Paragraph 94 and therefore denies them.

95. Certain allegations in Paragraph 95 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli denies the remaining allegations in Paragraph 95.

96. Mr. Shkreli admits that Retrophin acquired the rights to sell Thiola. Mr. Shkreli denies the remaining allegations in Paragraph 96.

97. Certain allegations in Paragraph 97 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli denies the remaining allegations in Paragraph 97.

98. Certain allegations in Paragraph 98 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 98 directed toward Mr. Mulleady and therefore denies them.

99. Mr. Shkreli admits that a restricted distribution system for Daraprim had been put in place prior to Vyera's acquisition of Daraprim and that Vyera expanded the number of distributors that were distributing Daraprim. Mr. Shkreli denies the remaining allegations in Paragraph 99 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 99 directed toward the Company and Mr. Mulleady and therefore denies them.

**1. "Vyera's contractual restrictions prevent distributors from selling Daraprim to generic companies"**

100. Certain allegations in Paragraph 100 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 100 directed toward the Company and therefore denies them.

101. Certain allegations in Paragraph 101 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 101 directed toward the Company and therefore denies them.

102. Mr. Shkreli admits that Vyera has a contractual relationship with ICS and that the terms of that relationship are embodied in their contract, which is a document that speaks for itself. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 102 directed toward the Company and therefore denies them.

103. Certain allegations in Paragraph 103 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true

and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 103 directed toward the Company and therefore denies them.

104. Certain allegations in Paragraph 104 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 104 directed toward the Company and therefore denies them.

105. Certain allegations in Paragraph 105 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 105 directed toward the Company and therefore denies them.

106. Certain allegations in Paragraph 106 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 106 directed toward the Company and therefore denies them.

107. Certain allegations in Paragraph 107 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 107 directed toward the Company and therefore denies them.

108. Certain allegations in Paragraph 108 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 108 directed toward the Company and therefore denies them.

109. Certain allegations in Paragraph 109 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 109 directed toward the Company and therefore denies them.

110. Certain allegations in Paragraph 110 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 110 directed toward the Company and therefore denies them.

111. Certain allegations in Paragraph 111 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 111 directed toward the Company and therefore denies them.

112. Certain allegations in Paragraph 112 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information

to form a belief as to the truth of the remaining allegations in Paragraph 112 directed toward the Company and therefore denies them.

113. Certain allegations in Paragraph 113 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 113 directed toward the Company and therefore denies them.

**2. “Vyera’s contractual restrictions prevent downstream purchasers from selling Daraprim to generic companies”**

114. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 114 directed toward the Company and therefore denies them.

115. Certain allegations in Paragraph 115 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 115 directed toward the Company and therefore denies them.

116. Certain allegations in Paragraph 116 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 116 directed toward the Company and therefore denies them.

117. Certain allegations in Paragraph 117 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient

knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 117 directed toward the Company and therefore denies them.

118. Certain allegations in Paragraph 118 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 118 directed toward the Company and therefore denies them.

119. Certain allegations in Paragraph 119 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 119 directed toward the Company and therefore denies them.

120. Certain allegations in Paragraph 120 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 120 directed toward the Company and therefore denies them.

121. Certain allegations in Paragraph 121 purport to characterize or summarize from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli admits that Vyera entered into an agreement with Walgreens. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 121 directed toward the Company and therefore denies them.

122. Certain allegations in Paragraph 122 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 122 directed toward the Company and therefore denies them.

**3. “Vyera limits and monitors approved sales of Daraprim to prevent generic companies from obtaining it”**

123. Mr. Shkreli denies the allegations in Paragraph 123. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 123 directed toward the Company and Mr. Mulleady, and therefore denies them.

124. Mr. Shkreli denies the allegations in Paragraph 124. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 124 directed toward the Company and Mr. Mulleady, and therefore denies them.

125. Certain allegations in Paragraph 125 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 125 directed toward the Company and therefore denies them.

126. Certain allegations in Paragraph 126 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 126 directed toward the Company and therefore denies them.



127. Certain allegations in Paragraph 127 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 127 directed toward the Company and therefore denies them.

128. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 128 directed toward the Company and therefore denies them.

129. Certain allegations in Paragraph 129 purport to characterize, summarize, or quote from selected portions of one or more documents or recordings, which speak for themselves. Mr. Shkreli refers to those documents or recordings for a true and complete statement of their contents.

130. Certain allegations in Paragraph 130 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 130 directed toward Mr. Mulleady and Mr. Mithani, and therefore denies them.

131. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 130 and therefore denies them.

132. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 132, which are solely directed toward the Company and Mr. Mulleady, and therefore denies them.

133. Certain allegations in Paragraph 133 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient

knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 133 and therefore denies them.

**4. “Defendants’ generic-blocking restrictions prevent generic competitors from purchasing Daraprim and have no legitimate rationale”**

134. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 134, directed solely toward the Company, and therefore denies them.

135. Certain allegations in Paragraph 135 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 135, directed solely toward the Company, and therefore denies them.

136. Paragraph 136 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 136. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 135, directed solely toward the Company, and therefore denies them.

137. Mr. Shkreli denies the allegations in Paragraph 137.

138. Certain allegations in Paragraph 138 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli denies the allegations in Paragraph 138 directed toward Mr. Shkreli.

139. Certain allegations in Paragraph 139 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli admits that,

in 2015, the Senate Special Committee on Aging launched an investigation into price increases for certain drugs. Mr. Shkreli denies the remaining allegations in Paragraph 139.

140. Certain allegations in Paragraph 140 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli denies the allegations in Paragraph 140, except admits that certain Vyera employees testified before the Senate.

141. Mr. Shkreli denies the allegations in Paragraph 141.

142. Paragraph 142 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 142. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 142 and therefore denies them.

143. Certain allegations in Paragraph 143 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 130 directed toward the Company, and therefore denies them.

**B. “Defendants Enter Exclusive Agreements With API Manufacturers to Block Generic Companies’ Access to Pyrimethamine API Supply”**

144. Mr. Shkreli denies the allegations in Paragraph 144 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 144 directed toward the Company and Mr. Mulleady, and therefore denies them.

145. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 145 and therefore denies them.

146. To the extent that the allegations in Paragraph 146 purport to describe the FDA's API approval process, such allegations constitute legal conclusions to which no response is required. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 146 and therefore denies them.

147. Certain allegations in Paragraph 147 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 147 and therefore denies them.

148. Mr. Shkreli denies the allegations in Paragraph 148.

**1. "Vyera locks up the only manufacturer with an FDA-approved manufacturing process for pyrimethamine API"**

149. Mr. Shkreli admits that, as of 2015, Fukuzyu and Ipca Laboratories Ltd. had filed Drug Master Files ("DMF") with the FDA. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 149, which are directed solely toward the Company, and therefore denies them.

150. Certain allegations in Paragraph 150 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 150, which are directed solely toward the Company, and therefore denies them.

151. Mr. Shkreli admits that Fukuzyu's pyrimethamine API is approved by the FDA. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 151, which are directed solely toward the Company, and therefore denies them.

152. Certain allegations in Paragraph 152 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 152, which are directed solely toward the Company, and therefore denies them.

153. The allegations in Paragraph 153 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 153, which are directed solely toward the Company, and therefore denies them.

154. Certain allegations in Paragraph 154 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 154, which are directed solely toward the Company, and therefore denies them.

155. Certain allegations in Paragraph 155 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient

knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 155, which are directed solely toward the Company, and therefore denies them.

156. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 156, which are directed solely toward the Company, and therefore denies them.

157. Certain allegations in Paragraph 157 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 157, which are directed solely toward the Company, and therefore denies them.

158. Paragraph 158 purports to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli admits that the Company has an agreement with Fukuzyu that remains in effect.

**2. “Defendants poach a second API manufacturer from generic competitors”**

159. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 159, which are directed solely toward the Company, and therefore denies them.

160. To the extent that Paragraph 160 makes allegations regarding RL Fine’s plans, business or experience, manufacturing process, ability to obtain FDA approval, and ability to supply pyrimethamine API for sale in the United States, Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of such allegations and therefore denies them. Mr. Shkreli denies the remaining allegations in Paragraph 160.

161. Mr. Shkreli denies the allegations in Paragraph 161.

162. Certain allegations in Paragraph 162 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 162 directed toward Mr. Mulleady and therefore denies them.

163. Certain allegations in Paragraph 163 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 163, which are directed solely towards the Company and Mr. Mulleady, and therefore denies them.

164. Certain allegations in Paragraph 164 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 164, which are directed solely toward the Company, and therefore denies them.

165. Certain allegations in Paragraph 165 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 165, which are directed solely toward the Company, and therefore denies them.

166. Certain allegations in Paragraph 166 purport to characterize or summarize one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true

and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 166, which are directed solely toward the Company, and therefore denies them.

167. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 167, which are directed solely toward the Company, and therefore denies them.

168. To the extent that Paragraph 168 makes allegations regarding supply interruptions at Fukuzyu, Fukuzyu's capacity to produce pyrimethamine API, and Fukuzyu's supply of pyrimethamine API to other manufacturers, Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of these allegations. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 168, which are directed solely toward the Company, and therefore denies them.

169. To the extent that Paragraph 169 alleges that RL Fine did not "take any further steps to conform its process to FDA requirements," Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of such allegation and on that basis denies it. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 169, which are directed solely toward the Company, and therefore denies them.

170. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 170, which are directed solely toward the Company, and therefore denies them.

171. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 171, which are directed solely toward the Company, and therefore denies them.



172. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 172, which are directed solely toward the Company, and therefore denies them.

173. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 173, which are directed solely toward the Company, and therefore denies them.

174. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 174, which are directed solely toward the Company, and therefore denies them.

175. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 175, which are directed solely toward the Company, and therefore denies them.

**C. “Vyera Enters Data-Blocking Agreements to Mask the True Size of the Pyrimethamine Market”**

176. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 176, which are directed solely toward the Company, and therefore denies them.

177. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 177, and therefore denies them.

178. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 178, and therefore denies them.

179. Mr. Shkreli denies the allegations in Paragraph 179.

180. Mr. Shkreli admits that Vyera Pharmaceuticals, LLC and Phoenixus AG are privately-held companies. Mr. Shkreli states that Vyera is required by law to report aspects of

Daraprim's distribution, including to government regulatory bodies. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 180 and therefore denies them.

181. Mr. Shkreli denies the allegations in Paragraph 181.

182. Mr. Shkreli denies the allegations in Paragraph 182.

183. The allegations in Paragraph 183 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 183, which are directed solely toward the Company, and therefore denies them

184. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 184, which are directed solely toward the Company, and therefore denies them.

185. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 185, which are directed solely toward the Company, and therefore denies them.

186. The allegations in Paragraph 186 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 186, which are directed solely toward the Company, and therefore denies them.

187. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 187, which are directed solely toward the Company, and therefore denies them.

188. Certain allegations in Paragraph 188 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 188, which are directed solely toward the Company, and therefore denies them.

189. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 189 and therefore denies them.

190. Mr. Shkreli admits that Vyera has no obligation to publicly report its Daraprim sales. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 173 and therefore denies them

**VI. “Defendants’ Anticompetitive Conduct Successfully Delayed and Excluded Numerous Potential Generic Competitors”**

191. Mr. Shkreli denies the allegations in Paragraph 191.

A. [REDACTED]

192. To the extent that Paragraph 192 asserts allegations speculating about [REDACTED] Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of such allegations and on that basis denies them. Mr. Shkreli denies the remaining allegations in Paragraph 192.

193. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 193 and therefore denies them.

194. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 194 and therefore denies them.

195. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 195 and therefore denies them.

196. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 196 and therefore denies them.

197. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 197 and therefore denies them.

198. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 198 and therefore denies them.

199. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 199 and therefore denies them.

200. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 200 and therefore denies them.

201. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 201 and therefore denies them.

202. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 202 and therefore denies them.

203. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 203 and therefore denies them.

204. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 204 and therefore denies them.

205. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 193 and therefore denies them.

206. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 206 and therefore denies them.

207. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 207 and therefore denies them.

208. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 208 and therefore denies them.

209. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 209 and therefore denies them.

210. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 210 and therefore denies them.

211. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 211 and therefore denies them.

212. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 212 and therefore denies them.

213. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 213 and therefore denies them.

214. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 214 and therefore denies them.

215. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 215 and therefore denies them.

216. Mr. Shkreli admits the allegations in Paragraph 216.

217. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 217 and therefore denies them.

218. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 218 and therefore denies them.

219. Mr. Shkreli denies the allegations in Paragraph 219 directed toward Mr. Shkreli. To the extent that Paragraph 219 asserts allegations speculating about [REDACTED], Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of such allegations and on that basis denies them.

220. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 220 and therefore denies them.

**B. “ [REDACTED] ”**

221. Mr. Shkreli denies the allegations in Paragraph 221 directed toward Mr. Shkreli. To the extent that Paragraph 221 asserts allegations speculating about [REDACTED] Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of such allegations and therefore denies them.

222. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 222 and therefore denies them.

223. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 223 and therefore denies them, except admits that Daraprim has no patent protection.

224. To the extent that the allegations in Paragraph 224 purport to describe the FDA’s approval process, such allegations constitute legal conclusions to which no response is required.

Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 224 and therefore denies them.

225. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 225 and therefore denies them.

226. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 226 and therefore denies them.

227. Mr. Shkreli admits that Ipca had a U.S. DMF for pyrimethamine. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 227 and therefore denies them.

228. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 228 and therefore denies them.

229. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 229 and therefore denies them.

230. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 230 and therefore denies them.

231. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 231 and therefore denies them.

232. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 232 and therefore denies them.

233. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 233 and therefore denies them.

234. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 234 and therefore denies them.

235. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 235 and therefore denies them.

236. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 236 and on that basis denies them.

237. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 237 and therefore denies them.

238. Mr. Shkreli denies the allegations in Paragraph 238 directed toward Mr. Shkreli. To the extent that Paragraph 238 asserts allegations speculating about [REDACTED] Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of such allegations and therefore denies them.

C. “[REDACTED]”

239. Mr. Shkreli denies the allegations in Paragraph 239 directed toward Mr. Shkreli. To the extent that Paragraph 239 asserts allegations speculating about [REDACTED], Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of such allegations and therefore denies them.

240. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 240 and therefore denies them.

241. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 241 and therefore denies them.

242. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 242 and therefore denies them.

243. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 243 and therefore denies them.



244. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 244 and therefore denies them.

245. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 245 and therefore denies them.

246. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 246 and therefore denies them.

247. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 247 and therefore denies them.

248. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 248 and therefore denies them.

249. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 249 and therefore denies them.

250. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 250 and therefore denies them.

251. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 251 and therefore denies them.

252. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 252, which are directed solely toward the Company, and therefore denies them.

253. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 253, which are directed solely toward the Company, and therefore denies them.

254. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 254, which are directed solely toward the Company and Mr. Mulleady, and therefore denies them.

255. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 255, which are directed solely toward the Company and Mr. Mulleady, and therefore denies them.

256. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 256, which are directed solely toward the Company and Mr. Mulleady, and therefore denies them.

257. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 257, which are directed solely toward the Company, and therefore denies them.

258. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 258 and therefore denies them.

259. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 259 and therefore denies them.

260. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 260 and therefore denies them.

261. Mr. Shkreli denies the allegations in Paragraph 261 directed toward Mr. Shkreli. To the extent that Paragraph 261 asserts allegations speculating about [REDACTED], Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of such allegations and on that basis denies them.

**D. “Mylan N.V.”**

262. Mr. Shkreli admits that Mylan is one of the largest generic pharmaceutical companies in the world. Mr. Shkreli denies the remaining allegations in Paragraph 262.

263. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 263 and therefore denies them.

264. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 264 and therefore denies them.

265. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 265 and therefore denies them.

266. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 266 and therefore denies them.

**E. “Other generic companies”**

267. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 267 and therefore denies them.

268. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 268 and therefore denies them.

269. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 269 and therefore denies them.

270. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 270 and therefore denies them.

271. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 271 and therefore denies them.

272. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 272, which are directed solely toward the Company, and therefore denies them.

**VII. “Defendants’ Foreclosure of Generic Entry Caused Consumers to Pay Higher Prices”**

273. Mr. Shkreli denies the allegations in Paragraph 273.

274. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 274 and therefore denies them.

275. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 275 and therefore denies them.

276. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 276 and therefore denies them.

277. Mr. Shkreli denies the allegations in Paragraph 277.

278. Mr. Shkreli denies the allegation in Paragraph 278 that “Defendants’ anticompetitive conduct has delayed the introduction of . . . price competition to the detriment of consumers and other purchasers of Daraprim.” Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 278 and therefore denies them.

279. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 279, which are directed solely toward the Company, and therefore denies them.

280. Mr. Shkreli denies the allegations in Paragraph 280.

281. Mr. Shkreli denies the allegations in Paragraph 281.

282. Mr. Shkreli denies the allegations in Paragraph 282.

283. Mr. Shkreli denies the allegations in Paragraph 283.

284. Mr. Shkreli denies the allegations in Paragraph 284 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 284 and therefore denies them.

285. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 285, and therefore denies them.

286. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 286 and therefore denies them.

287. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 286 and therefore denies them.

288. Mr. Shkreli denies the allegations in Paragraph 288.

289. Mr. Shkreli denies the allegations in Paragraph 289.

290. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 290, which are directed solely toward the Company, and therefore denies them.

291. Mr. Shkreli denies the allegations in Paragraph 291.

292. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 292, which are directed solely toward the Company, and therefore denies them.

293. Mr. Shkreli denies the allegations in Paragraph 293.

294. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 292, which are directed solely toward Mr. Mulleady, and therefore denies them.

# **VIII. “Vyera Has Monopoly Power in a Relevant Market for FDA-Approved Pyrimethamine Products”**

295. Paragraph 295 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 295.

296. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 296, which are directed solely toward the Company, and therefore denies them.

297. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 297, which are directed solely toward the Company, and therefore denies them.

298. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 298, which are directed solely toward the Company, and therefore denies them.

299. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 299, which are directed solely toward the Company, and therefore denies them.

300. Paragraph 300 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 300.

301. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 301, which are directed solely toward the Company, and therefore denies them.

302. Mr. Shkreli denies the allegations in Paragraph 302.

303. Certain allegations in Paragraph 303 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers

to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 303, which are directed solely toward the Company, and therefore denies them.

304. Mr. Shkreli denies the allegations in Paragraph 304.

305. Paragraph 305 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies those allegations. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 305 and therefore denies them.

306. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 306, which are directed solely toward the Company, and therefore denies them.

307. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 307, which are directed solely toward the Company, and therefore denies them.

308. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 308 and therefore denies them.

309. The allegations in Paragraph 309 purport to characterize, summarize, or quote from selected portions of one or more documents, which speak for themselves. Mr. Shkreli refers to those documents for a true and complete statement of their contents. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 309, which are directed solely toward the Company, and therefore denies them.

310. Paragraph 310 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 310.

311. Paragraph 311 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 311. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 311 and therefore denies them.

312. Paragraph 312 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 312. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 312 and therefore denies them.

313. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 313, which are directed solely toward the Company, and therefore denies them.

## **“COUNT I”**

### **“Monopoly Maintenance Against All Defendants”**

314. Mr. Shkreli hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

315. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 315, which are directed solely toward the Company, and therefore denies them.

316. Mr. Shkreli denies the allegations in Paragraph 316 that are directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 316 directed toward the Company and Mr. Mulleady and therefore denies them.

317. Mr. Shkreli denies the allegations in Paragraph 317.



318. Paragraph 318 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 318.

**“COUNT II”**

**“Agreements in Restraint of Trade (Restrictions and Limitations on Resale of Daraprim) Against All Defendants”**

319. Mr. Shkreli hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

320. Paragraph 320 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 320 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 320 directed toward the Company and Mr. Mulleady and therefore denies them.

**“COUNT III”**

**“Agreements in Restraint of Trade (API Supply Exclusivity Agreements) Against All Defendants”**

321. Mr. Shkreli hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

322. Paragraph 322 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 322 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 322 directed toward the Company and Mr. Mulleady and therefore denies them.

**“COUNT IV”**

**“A. Anticompetitive Contracts, Agreements and/or Arrangements in Violation of New York’s Donnelly Act Against All Defendants”**

323. Mr. Shkreli hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

324. Paragraph 324 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 324 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 324 directed toward the Company and Mr. Mulleady and therefore denies them.

325. Paragraph 325 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 325 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 325 directed toward the Company and Mr. Mulleady and therefore denies them.

326. Paragraph 326 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 326.

**“B. Illegality in Violation of New York Executive Law § 63(12) Against All Defendants”**

327. Mr. Shkreli hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

328. Paragraph 328 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 328.

**“COUNT V”**

**“A. Anticompetitive Contracts, Agreements and/or Arrangements  
in Violation of California’s Cartwright Act Against All Defendants”**

329. Mr. Shkreli hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

330. Paragraph 330 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 330 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 330 directed toward the Company and Mr. Mulleady and therefore denies them.

331. Paragraph 331 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 331 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 331 directed toward the Company and Mr. Mulleady and therefore denies them.

**“B. Anticompetitive Contracts, Agreements and/or Arrangements  
in Violation of California’s Unfair Competition Act Against All Defendants”**

332. Mr. Shkreli hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

333. Paragraph 333 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 333 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 333 directed toward the Company and Mr. Mulleady and therefore denies them.

334. Paragraph 334 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 334 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 334 directed toward the Company and Mr. Mulleady and therefore denies them.

## **“COUNT VI”**

### **“Anticompetitive Contracts, Combinations and/or Conspiracies in Violation of the Illinois Antitrust Act Against All Defendants”**

335. Mr. Shkreli hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

336. Paragraph 336 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 336 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 336 directed toward the Company and Mr. Mulleady and therefore denies them.

337. Paragraph 337 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 337.

## **“COUNT VII”**

### **“Unfair Methods of Competition and/or Unfair Acts or Practices in Violation of the North Carolina Unfair or Deceptive Practices Act Against All Defendants”**

338. Mr. Shkreli hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

339. Paragraph 339 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 339 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 339 directed toward the Company and Mr. Mulleady and therefore denies them.

340. Paragraph 340 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 340 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth

of the allegations in Paragraph 340 directed toward the Company and Mr. Mulleady and therefore denies them.

341. Paragraph 341 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 341.

342. Paragraph 342 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 342.

343. Paragraph 343 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 343.

### **“COUNT VIII”**

#### **“Violations of Ohio’s Valentine Act Against All Defendants”**

344. Mr. Shkreli hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

345. Paragraph 345 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 345.

### **“COUNT IX”**

#### **“A. Pennsylvania’s Unfair Trade Practices and Consumer Protection Law”**

346. Mr. Shkreli hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

347. Paragraph 347 contains allegations relating to Count IX(A) of the Complaint, which has been dismissed by the Court, and thus no response to those allegations is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 347.

348. Paragraph 348 contains allegations relating to Count IX(A) of the Complaint, which has been dismissed by the Court, and thus no response to those allegations is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 348.

349. Paragraph 349 contains allegations relating to Count IX(A) of the Complaint, which has been dismissed by the Court, and thus no response to those allegations is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 349.

350. Paragraph 350 contains allegations relating to Count IX(A) of the Complaint, which has been dismissed by the Court, and thus no response to those allegations is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 350.

351. Paragraph 351 (including its subparts (a)-(e)) contains allegations relating to Count IX(A) of the Complaint, which has been dismissed by the Court, and thus no response to those allegations is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 351 (including its subparts (a)-(e)).

352. Paragraph 352 contains allegations relating to Count IX(A) of the Complaint, which has been dismissed by the Court, and thus no response to those allegations is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 352.

353. Paragraph 353 contains allegations relating to Count IX(A) of the Complaint, which has been dismissed by the Court, and thus no response to those allegations is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 353.

**“B. Common Law Doctrine against Restraint of Trade”**

354. Mr. Shkreli hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

355. Paragraph 355 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 355.

356. Paragraph 356 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 356.

**“COUNT X”**

**“A. Anticompetitive Agreements in Violation of the  
Virginia Antitrust Act Against All Defendants”**

357. Mr. Shkreli hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

358. Paragraph 358 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 358 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 358 directed toward the Company and Mr. Mulleady and therefore denies them.

359. Paragraph 359 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 359 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 359 directed toward the Company and Mr. Mulleady and therefore denies them.

**“B. Monopoly Maintenance in Violation of the Virginia Antitrust Act”**

360. Mr. Shkreli hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

361. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 361, which are directed solely toward the Company, and therefore denies them.

362. Mr. Shkreli denies the allegations in Paragraph 362 directed toward Mr. Shkreli. Mr. Shkreli lacks sufficient knowledge or information to form a belief as to the truth of the

allegations in Paragraph 362 directed toward the Company and Mr. Mulleady and therefore denies them.

363. Mr. Shkreli denies the allegations in Paragraph 363.

364. Paragraph 364 states legal conclusions to which no response is required. To the extent a response is required, Mr. Shkreli denies the allegations in Paragraph 364.

### **GENERAL DENIAL**

Mr. Shkreli denies each and every allegation in the Complaint not specifically admitted or otherwise addressed above.

### **AFFIRMATIVE AND OTHER DEFENSES**

Without assuming any burden of proof that it would not otherwise bear, Mr. Shkreli asserts the following separate and additional affirmative and other defenses, all of which are pleaded in the alternative:

#### **First Defense**

The Complaint, and each and every claim stated therein, fails to state a claim against Mr. Shkreli upon which relief can be granted.

#### **Second Defense**

Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations and/or the doctrine of laches.

#### **Third Defense**

Plaintiffs' claims are barred, in whole or in part, because Mr. Shkreli's alleged conduct has not harmed competition, the competitive process, or consumers, and was lawful, procompetitive, and based on legitimate business and economic justifications.



#### **Fourth Defense**

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs have not alleged that Mr. Shkreli is presently engaged in ongoing or imminent violations of law, as required by, *inter alia*, Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b), and New York Executive Law Section 63(12), N.Y. Exec. Law § 63(12).

#### **Fifth Defense**

Plaintiffs' claims are barred, in whole or in part, insofar as the Federal Trade Commission purports to seek equitable monetary relief, since Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b), does not authorize the Federal Trade Commission to seek such relief.

#### **Sixth Defense**

Plaintiffs' claims are barred, in whole or in part, by the single entity doctrine, pursuant to which an antitrust conspiracy cannot be found among a corporation, its wholly-owned subsidiary and/or its officers and directors.

#### **Seventh Defense**

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs have not properly alleged a relevant product market.

#### **Eighth Defense**

Plaintiffs' claims are barred, in whole or in part, because Mr. Shkreli's alleged conduct did not lead to the acquisition or maintenance of monopoly power in any properly defined relevant antitrust market, and was lawful, procompetitive, and based on legitimate business and economic justifications.

### **Ninth Defense**

Plaintiffs' claims are barred, in whole or in part, because Mr. Shkreli's alleged conduct did not unreasonably restrain trade and was lawful, procompetitive, and based on legitimate business and economic justifications.

### **Tenth Defense**

Plaintiffs' claims are barred, in whole or in part, because any harm to competition complained of stems from the intricate multi-tiered regulatory regime that governs the production, sale, and manufacture of pharmaceutical products, including the Hatch-Waxman Act.

### **Eleventh Defense**

Plaintiffs' claims are barred, in whole or in part, because the injury complained of and the relief sought by Plaintiffs are the result of the actions or inaction of third-party generic manufacturers and/or government regulatory bodies, including without limitation the FDA.

### **Twelfth Defense**

The contemplated relief would not be in the public interest because it would, among other things, harm consumers.

### **Thirteenth Defense**

Plaintiffs' claims are barred, in whole or in part, because Mr. Shkreli did not enter into or sign any agreements with any distributors, hospitals, other downstream purchasers, or any API suppliers.

### **Fourteenth Defense**

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs are not direct purchasers of Daraprim, and have not suffered any antitrust injury.

#### **Fifteenth Defense**

Plaintiffs' claims are barred, in whole or in part, because Mr. Shkreli, as an individual, does not possess any market power or monopoly power.

#### **Sixteenth Defense**

Plaintiffs' claims are barred, in whole or in part, because Mr. Shkreli has no ability to control or direct the Company's business decisions, and therefore cannot be liable for any alleged illegal conduct by the Company under agency principles.

#### **Seventeenth Defense**

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs seek injunctive relief that is unreasonable, unduly punitive, and not narrowly tailored to the necessary relief.

#### **Eighteenth Defense**

Plaintiffs' claims for damages are barred, in whole or in part, because their damages as alleged are speculative and because of the impossibility of the ascertainment and allocation of those alleged damages.

#### **Nineteenth Defense**

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs lack standing to assert them.

#### **Twentieth Defense**

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs' injuries, if any, were caused, executed or approved in whole or in part by individuals or entities not under the control or direction of Mr. Shkreli.

#### **Twenty-First Defense**

Plaintiffs' claims are barred, in whole or in part, because Mr. Shkreli's conduct was justified, privileged, and/or not improper.

#### **Twenty-Second Defense**

Plaintiffs' claims are barred, in whole or in part, because this is not a "proper case" for the FTC to seek, and for the Court to issue, a permanent injunction, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. 53(b).

#### **Twenty-Third Defense**

Plaintiff's claims are barred, in whole or in part, because Plaintiffs' theory of reverse agency liability is not recognized by law.

#### **Twenty-Fourth Defense**

Plaintiffs' claims are barred, in whole or in part, because Mr. Shkreli has not received or benefitted from any ill-gotten gains as a result of the alleged conduct, and therefore any equitable monetary relief sought by Plaintiffs is an unlawful penalty.

#### **Twenty-Fifth Defense**

Plaintiffs' claims are barred, in whole or in part, because the underlying conduct did not concern or involve Mr. Shkreli, nor did he approve or ratify it.

#### **Twenty-Sixth Defense**

Plaintiffs' claims are barred, in whole or in part, because no consumers have been harmed by the conduct alleged.

#### **Twenty-Seventh Defense**

Plaintiffs' claims are barred, in whole or in part, because Mr. Shkreli was not a director or officer of the Company during the conduct complained of from February 2016 through the present.

### **Twenty-Eighth Defense**

Plaintiffs' claims are barred, in whole or in part, because Mr. Shkreli had no knowledge of the conduct alleged.

### **Twenty-Ninth Defense**

Plaintiffs' claims are barred, in whole or in part, because Mr. Shkreli did not consent to the conduct alleged.

### **Thirtieth Defense**

Mr. Shkreli adopts and incorporates by reference any applicable defense pleaded by any other Defendant not otherwise expressly set forth herein.

### **RESERVATION OF AFFIRMATIVE AND OTHER DEFENSES**

Mr. Shkreli reserves the right to assert and rely on additional affirmative and other defenses that may become available or apparent, and to amend his answer and/or defenses.

### **PRAYER FOR RELIEF**

WHEREFORE, Mr. Shkreli prays as follows:

1. That the Complaint be dismissed with prejudice;
2. That the Court enter judgment in favor of Mr. Shkreli; and
3. That the Court award further relief as deemed just and proper.

### **DEMAND FOR JURY TRIAL**

Mr. Shkreli demands a trial by jury on all issues so triable in this action.

Dated: September 15, 2020

Respectfully submitted,

By: /s/ Christopher H. Casey  
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